(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 901 776 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
17.03.1999 Bulletin 1999/11

(51) Int Cl.[6]: **A61F 2/06**, A61M 25/10

(21) Application number: **98830260.0**

(22) Date of filing: **29.04.1998**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **05.09.1997 IT BS970077**

(71) Applicant: **Invatec S.r.l**
25062 Concesio (Brescia) (IT)

(72) Inventor: **Venturelli, Andrea**
25062 Concesio (Brescia) (JP)

(74) Representative: **Manzoni, Alessandro**
MANZONI & MANZONI,
UFFICIO INTERNAZIONALE BREVETTI,
P.le Arnaldo 2
25121 Brescia (IT)

(54) System for introducing and positioning expandable stents

(57) This invention relates to a catheter structure for dilating and for positioning stents, comprising a catheter having an inflatable ballonn, and wherein two collars (14) are fixed around the said catheter inside the balloon ad intended to define two annular shoulders (15) one in front of the other and spaced apart in parallel. A tubular adapter (17) is arranged around the said chateter portion between the said collars, and the said balloon, when empty, is wrapped around the collars with the said tubular adapter comprised between same.

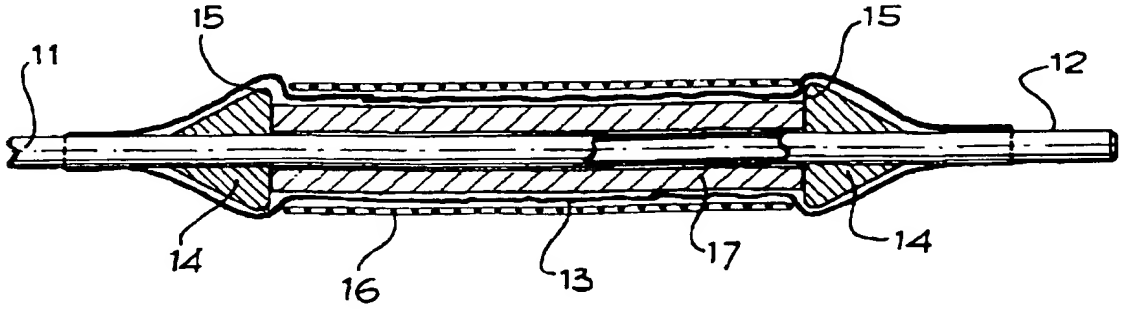

Fig.1

EP 0 901 776 A1

Printed by Jouve, 75001 PARIS (FR)

Description

[0001] The present invention pertains to the instruments for th introduction and th positioning of mechanically dilating stent in the ducts or lumina of a live, either human or animal body.

[0002] Stcnts are tubular molds which are made of biocompatible materials and are contracted on their introduction and then they dilate for their stable insertion into the desired duct or lumen. Some types of stcnts dilate mechanically, and for their insertion they require the use of an expandable element arranged along the introducing instrument and acting inside the stent.

[0003] As the instrument for the introduction of mechanically dilating stents, a catheter having an inflatable balloon at its distal end of the type already used may also be used, e.g., for dilating arterial ducts or other lumina in a live body. Therefore, for the introduction operation, the balloon, empty, is wrapped tightly around a corresponding zone of the catheter, and the stent, in its turn, is arranged tightly around the balloon in order to remain fixed there during the introduction into a lumen.

[0004] In general then, the catheter, at the balloon, has a radiopaque marker in order to be able to control the position of the catheter and, therefore, that of the balloon in the duct or lumen in question.

[0005] However the requirements of a catheter for the simple dilation of ducts or lumina most often are incompatible with those of a catheter for the positioning of a stent, which is why specific catheters would be needed for one or the other operation.

[0006] A dilating catheter, for example, for angioplasty procedures, or the like, must have a small diameter, a low coefficient of surface friction, and a highly resistant balloon. On the other hand, a catheter for the positioning of stents must have a remarkable friction, at least at the balloon, be made of a material having a surface that is adapted to the interior of the closed, i.e., contracted stent, and have a diameter of the balloon, when closed, i.e., wrapped around the catheter, that is at least slightly greater than the internal diameter of the closed stent. All this is to hold the stent and to prevent its loss during the insertion in a duct or lumen.

[0007] Otherwise, a diameter in the zone of the catheter, including the closed balloon wrapped there, that is smaller than the internal diameter of the closed stent that is applied there may cause:

- a so-called overlapping resulting from a corrugation and an overlapping of some parts of the stent with possible deformation of its structure, if the stent is contracted too tightly in order to adhere to such a zone; or
- an improper fixing of the stent with the possibility of losing it during the introduction if the stent, although suitably and correctly closed, does not adhere to the too-small outer surface of the catheter plus closed balloon.

[0008] Starting from these representative premises of the state of the art, the object of the present invention is to provide a valid solution to the problems mentioned abov and to corr spondingly provide an improved catheter structure, which is reliable for a correct arrangement of the stent contracted around the closed balloon and which makes it possible to reduce, if not to eliminate, the possibilities of release and loss of the stent during the phase of introduction into the duct or lumen in which it is inserted.

[0009] Another object of the present invention is to propose a catheter structure that can be used advantageously either as a catheter for dilating or a catheter for positioning expandable stents.

[0010] These objects are accomplished with a catheter structure for positioning stents according to claim 1.

[0011] In practice, the contracted stent is thus arranged and is held positively between two shoulders, prevented from sliding axially and thus from being lost, and this is independent of the actual diameter of the catheter, of the material with which the balloon is made and of the degree of friction offered by the said balloon.

[0012] In addition, the diameter of the catheter portion between shoulders may be adapted by increasing it with the application of a tubular adapter.

[0013] Greater details of the present invention, as well as its other aspects and advantages, shall become more evident from the description below with reference to the attached drawings, in which:

Figure 1 shows the partial view of a catheter according to the present invention with wrapped balloon and stent contracted around the balloon between two conical collars;

Figure 2 shows a similar view of the catheter of Figure 1, but with the balloon inflated and the stent dilated;

Figure 3 shows part of a catheter with biconical collars; and

Figures 4 and 5 show views that are similar to those of Figures 1 and 2, but in which the collars are defined by spherical elements.

[0014] In the said drawings, the catheter is indicated globally by 11 and has, in the known manner, an inflatable balloon 13 on its distal section 12.

[0015] Two collars 14, which are spaced apart and delimit two annular shoulders 15, one in front of the other, around the catheter, are applied on the catheter part that is within the balloon.

[0016] The two collars 14 may preferably be conical, with opposite conicities, as shown in Figures 1 and 2, one towards the distal end 12 of the catheter and the other in the opposite direction, in order to facilitate the introduction and the extraction of the catheter in a duct or lumen of a body. As an alternative, the said collars 14 may be biconical as shown in Figure 3, or spherical as shown in Figures 4 and 5.

[0017] The said collars 14 may be made of a radiopaque material in order to form markers which make it possible to find th position of the catheter in the duct or lumen, in which it is inserted.

[0018] The distance between the two collars and, therefore, between the annular shoulders 15 is at least slightly greater than the length of a stent 16 to be used and to be inserted with the dilating catheter described.

[0019] Therefore, to use this catheter in the positioning of an expandable stent 16, the empty balloon is wrapped tightly on the collars 14 and around the part of the catheter comprised between said collars. The stent 16 is then placed and contracted around the balloon and is held in the space comprised between the two annular shoulders 15 defined by the collars 14 as shown in Figures 1, 2 and 4.

[0020] If the catheter plus the balloon wrapped thereon has a suitable diameter, the contracted stent is adapted to the outer surface of the closed balloon with no overlapping and, moreover, positively held axially between the shoulders 15 and radially within the peripheral outline of the collars.

[0021] In the case of a particularly thin catheter, as in the catheters used for angioplasty, and in which the external diameter of the catheter plus the empty balloon wrapped thereon may be much smaller than the internal diameter of the contracted, i.e., closed, stent, without overlapping around the catheter part comprised between the two collars 14, a tubular adapter 17 held between the two shoulders 15 may be applied and so as to artificially increase the diameter of the catheter as shown in the drawings. Therefore, even in this case, the stent may be applied correctly on the catheter without the possibility of loss during the introduction into the duct or lumen in question.

[0022] Figures 2 and 5 of the drawings illustrate the condition of expansion of the balloon and of dilation of the stent for the release of same at the time of its insertion.

Claims

1. Catheter structure for dilating and for positioning stents, comprising a catheter having a inflatable balloon, **characterized**:

   - by two collars (14) fixed around the catheter part inside the said balloon and intended to define two annular shoulders (15) one in front of the other and spaced apart in parallel;
   - by a tubular adapter (17) arranged around the said catheter portion between the said collars; and
   - in that the said balloon, when empty, is wrapped around the collars with the tubular adapter comprised between same, the shoulders forming bilateral axial closing means for a stent that is arranged and contracted around the empty and wrapped balloon.

2. Cathet r structure in accordance with claim 1 in which the collars are conical with opposite conicities, one towards a distal end of the catheter and the other in the opposite direction.

3. Catheter structure in accordance with claim 1 in which the said collars are each biconical.

4. Catheter structure in accordance with claim 1 in which the said collars are spherical.

5. Catheter structure in accordance with the claims 2-4 in which the said collars are made of a radiopaque material.

6. Catheter structure in accordance with claim 1 in which the tubular adapter (17) is held between the said shoulders and is intended to increase the external diameter of the said catheter.

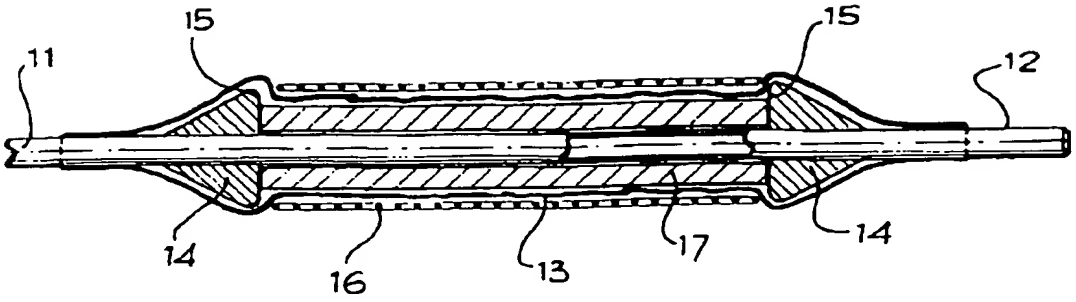

Fig.1

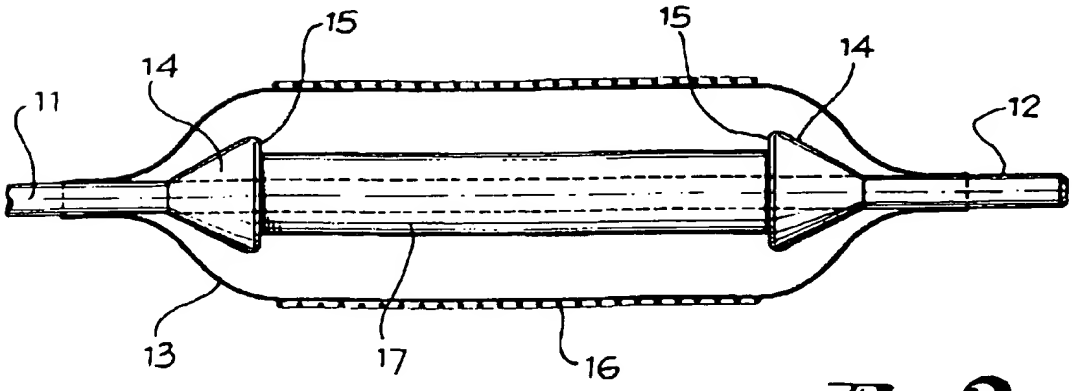

Fig.2

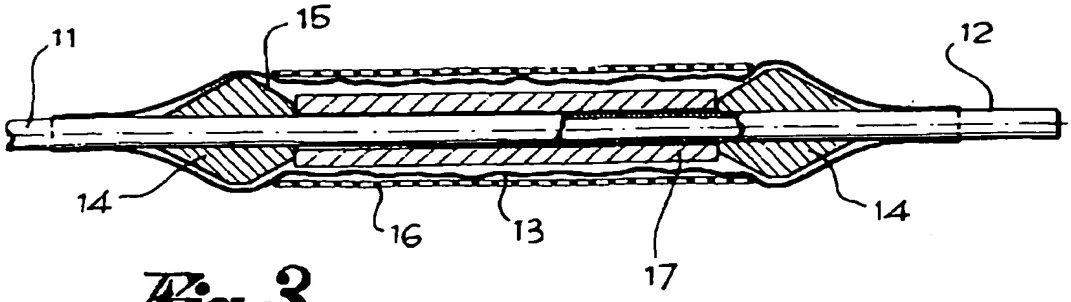

Fig.3

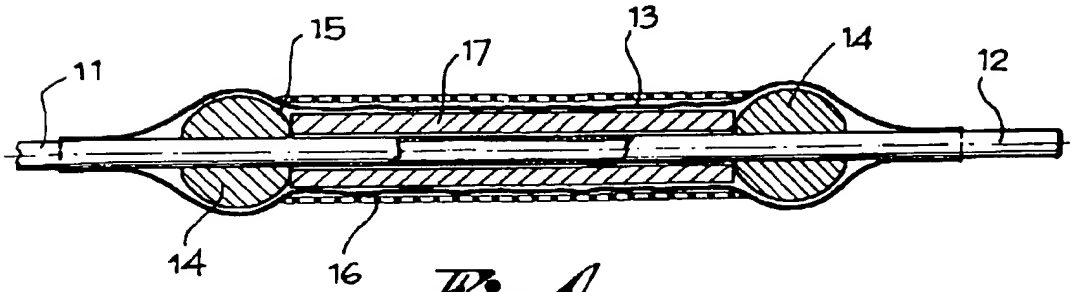

Fig.4

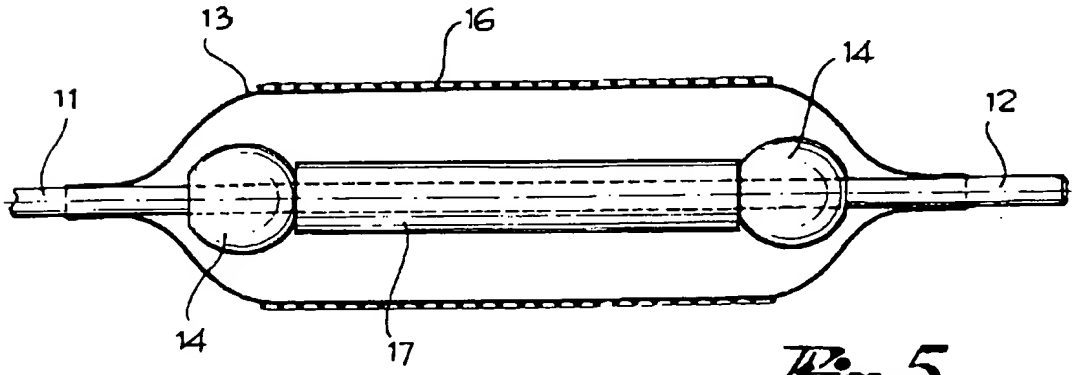

Fig.5

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 98 83 0260

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	EP 0 770 366 A (FIGULLA HANS REINER PROF DR) 2 May 1997 * column 2, line 20 - column 4, line 21 * * figure 2 *	1-5	A61F2/06 A61M25/10
A	WO 96 12517 A (APPLIED VASCULAR ENG INC) 2 May 1996 * page 5, line 11-17 * * page 14, line 10-30 * * figure 8 *	1-4	
A	EP 0 707 837 A (SHEIBAN IMAD ;CORDIS EUROP (NL)) 24 April 1996 * column 2, line 48 - column 4, line 2 * * figures 2,5 *	1,5	
A	US 4 776 337 A (PALMAZ JULIO C) 11 October 1988 * column 7, line 52-67; figure 3 *	1	
A	US 5 514 093 A (ELLIS LOUIS G ET AL) 7 May 1996 * column 10, line 44-55 * * figures 2,3 *	1,6	TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61F A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
MUNICH	18 November 1998	Bichlmayer, K-P

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 98 83 0260

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

18-11-1998

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0770366 A	02-05-1997	DE 19540084 A	30-04-1997
		AT 157237 T	15-09-1997
		DE 59600020 D	02-10-1997
		ES 2106645 T	01-11-1997
WO 9612517 A	02-05-1996	AU 3957195 A	15-05-1996
		CA 2202257 A	02-05-1996
		EP 0787020 A	06-08-1997
		JP 8164210 A	25-06-1996
EP 0707837 A	24-04-1996	NL 9401744 A	03-06-1996
		NL 9401758 A	03-06-1996
		NL 9500284 A	03-06-1996
		JP 8238322 A	17-09-1996
		US 5632760 A	27-05-1997
		EP 0707865 A	24-04-1996
		JP 8206217 A	13-08-1996
		NL 9500283 A	03-06-1996
US 4776337 A	11-10-1988	US 4733665 A	29-03-1988
		AU 591942 B	21-12-1989
		AU 6488286 A	14-05-1987
		BR 8605658 A	15-12-1987
		CA 1281504 A	19-03-1991
		CA 1281505 A	19-03-1991
		CA 1338303 B	07-05-1996
		EP 0221570 A	13-05-1987
		GR 3001410 T	25-09-1992
		JP 2731642 B	25-03-1998
		JP 4357949 A	10-12-1992
		JP 1719657 C	14-12-1992
		JP 4006377 B	05-02-1992
		JP 62231657 A	12-10-1987
		JP 9276302 A	28-10-1997
		US 5102417 A	07-04-1992
		US 4739762 A	26-04-1988
US 5514093 A	07-05-1996	US 5676654 A	14-10-1997

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82